

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The study of the effect of foot reflexology on the shoulder, neck and waist pains as well as refreshment of the nurses.

Protocol summary

Study aim

Determining the effect of foot reflexology on the shoulder, neck and waist pains as well as refreshment of the nurses.

Design

Clinical trial with a control group, one-blinded, randomized

Settings and conduct

Nurses of the Shahid Niaky hospital of Ahwaz city are considered the intervention group and nurses of the 580 hospital of Dezful city as the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria : 1- should not be athlete. 2 - BMI should be between 18 and 25 . 3- The mean age should be between 20 and 50 years.

Intervention groups

The study of the effect of foot reflexology on the shoulder, neck and waist pains as well as refreshment of the nurses.

Main outcome variables

Pain intensity , Fatigue intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180911041006N1**

Registration date: **2019-01-22, 1397/11/02**

Registration timing: **retrospective**

Last update: **2019-01-22, 1397/11/02**

Update count: **0**

Registration date

2019-01-22, 1397/11/02

Registrant information

Name

Hojatolah Mirzaeenia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 2889

Email address

mirzaeenia.h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-09-10, 1397/06/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of the effect of foot reflexology on the shoulder, neck and waist pains as well as refreshment of the nurses.

Public title

The effect of the foot reflexology on the pain and fatigue of nurses.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

BMI should be between 18 and 25. Should not be athlete. Age range should be between 20 to 50 years. The nursing staff suffering from backache as well as shoulder and neck pain. Nursing staff with fatigue.

Exclusion criteria:

Having a foot ulcer. Having peripheral neuropathy.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz University of Medical Sciences

Street address

Room 4 ,Ground Floor , deputy of Research and Technology Dvelopment of ahwaz Jundishapur University of Medical Sciences , University of Ahwaz

City

Ahwaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-06-08, 1397/03/18

Ethics committee reference number

IR.AJUMS.SER.1397.214

Health conditions studied

1

Description of health condition studied

Skeletal and muscular pain and fatigue

ICD-10 code

M63

ICD-10 code description

Diseases of the musculoskeletal system and connective tissue

Primary outcomes

1

Description

The backache intensity

Timepoint

Before the intervention and ten days after that.

Method of measurement

The visual analogue scale

2

Description

The fatigue intensity

Timepoint

Before the intervention and ten days after that.

Method of measurement

Fatigue questionnaire sofi -20

3

Description

The neck pain intensity.

Timepoint

Before the intervention and ten days after that.

Method of measurement

Visual Analogue Scale

4

Description

The shoulder pain intensity.

Timepoint

Before the intervention and ten days after that.

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

quality of life

Timepoint

Before the intervention and one month after the end of the intervention

Method of measurement

SF-36 Questionnaire

Intervention groups

1

Description

Intervention group: For the intervention group, according to the location of pain, a 9-sessions foot reflexology protocol have been applied on the test group by the contributing researcher (after passing the training and acquiring skills) under supervision of the physiotherapist (for 3 weeks and 3 sessions per 30 minutes each week). The reflexology process will be such that the study unit is

asked to lie on the examination bed in a quiet and bright room, close its eyes and place in a completely relaxed position. Then, after mild foot massage, the heel of the left foot would be kept pressed and bend it to the right and directly pressed (the point affecting the fatigue) with a thumb on the solar grid (Solar Plexus). Then, the massager get the patient's leg with One hand and by use of thumb of another hand, apply pressure on the reflex points of the waist, spine, ankle or any organ that is based on the Nordic questionnaire for the pain. By the individual, the alternating wave forms and smokes come in and out. This will be done within 30 minutes for both legs. Then they were asked to use fluids for 24-48 hours after each session. It should be noted that the reflexology of the female nurses is carried out by the implementer and under the supervision of a specialist physiotherapist for the protection of the Islamic components by a collaborator and in a closed environment, and reflexology of the men. control group:

Category

Rehabilitation

2

Description

Control group: In the control group, no intervention will be performed and they will only with the experimental group before and after the intervention, the Nordic and VAS questionnaires and the checklist of

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid niaky hospital

Full name of responsible person

Hojat Alah Mirzaeenia

Street address

Lashkar St , Blvd. Ghods , next to the mosque of Amiralmomentin , Shahid niaky hospital

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2

Recruitment center

Name of recruitment center

Dezful Army 580 Hospital

Full name of responsible person

Hojat Alah Mirzaeenia

Street address

Dezful , Army 580 Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology .

Street address

Ground floor , Ahvaz University of Medical Sciences Jundishapur Health Services , Univercity of Ahvaz , Assistant Professor of Research and Technology

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Hojat Alah Mirzaeenia

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Hojat Alah Mirzaeenia

Position

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Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

data of Pain intensity and fatigue severity

When the data will become available and for how long

Summer of 1398

To whom data/document is available

only researchers

Under which criteria data/document could be used

Researchers after obtaining permission from the research team

From where data/document is obtainable

Hojatollah Mirzaeenia

What processes are involved for a request to access data/document

Accept permission by email and related explanations regarding how to use the data

Comments